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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/821,125
Filing Date: April 08, 2004
Appellant(s): FAVET ET AL.

Mark A. Hollingsworth
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 21 April 2008 appealing from the Office action mailed 18 March 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,074,301	Gill	12-1991

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Gill (U.S. 5,074,301). Regarding claims 1-6 and 11, Gill discloses (col. 3, lines 49-52; Figure 1) a system (1) "designed to be implantable in a patient and includes a pulse module (10) and appropriate leads fro connecting module to a patient's heart (11)." The examiner considers this to be a housing configured for implantation in a patient and a

lead system comprising one or more lead electrodes. A pacemaker is provided (col. 4, lines 22-55; Figure 2) that comprises "circuitry for atrial pacing (24), ventricular pacing (34), atrial sensing (25), ventricular sensing (35) and telemetry (30). In addition, pacemaker (17) includes a control block (39) which includes an interface to microprocessor (19)." The examiner considers this to be energy delivery circuitry provided in the housing, detection circuitry and control circuitry coupled to the energy delivery circuitry and the detection circuitry. Gill further discloses (col. 6, lines 1-16; Figure 4B) an ECG trace outlining a "defibrillation shock sequence in which the defibrillation shock therapy is preceded by a pre-shock atrial pace. At (80), a VT/VF [ventricular fibrillation or ventricular tachycardia] arrhythmia has developed. Prior to the delivery of defibrillation shock therapy at (82), a pacing pulse is delivered to the atrium at (81). The timing of the pacing pulse is such that it renders the atrium depolarized during the subsequent delivery of the shock." As shown at (83), "the defibrillation shock has succeeded in reverting the VT/VF arrhythmia and normal sinus rhythm is present." The examiner considers this to be an energy delivery circuitry that is capable of delivering a therapy to treat a tachyarrhythmia, in response to detection of a tachyarrhythmia requiring treatment. A defibrillation shock (col. 6, lines 34-44; Figure 4C) "which has succeeded in reverting the VT/VF arrhythmia, is followed by a post-shock delay, as shown at (93). At (94), asystole is detected and thus bradycardia pacing is commenced, about 4 seconds after the delivery of the defibrillation shock. By this time, the pro-arrhythmic effect of a premature recommencement of bradycardia support pacing immediately post reversion has been avoided, as there has been

sufficient time for the patient's heart's conduction system to become reorganized and susceptible to bradycardia support pacing." The examiner considers this to be energy delivery circuitry that is capable of delivering a non-physiological, life sustaining pacing therapy in response to detection of cardiac asystole.

3. Regarding claims 7-10 and 12, Gill discloses, (col. 1, lines 22-32) "The term therapy as used herein includes the processes used between the detection and the reversion of a tachyarrhythmia and includes the actions of antitachycardia pacing, cardioversion and/or defibrillation shocks. The term cardioversion refers to the discharge of electrical energy into the cardiac tissue in an attempt to terminate or revert a tachyarrhythmia. This may take the form of a high energy discharge (up to 40 Joules or more) or a low energy discharge (less than 1 Joule). The discharge may be monophasic or biphasic but is not restricted to these waveforms." The examiner considers this to teach a tachyarrhythmia therapy that includes anti-tachycardia pacing therapy, treatment of cardiac fibrillation and bi- or monophasic defibrillation therapy.

4. Further regarding claim 12, Gill discloses, (col. 4, lines 1-5) "Defibrillator (16) produces a high voltage to charge its capacitors and then discharges them in response to control signals from microprocessor. A defibrillator electrode lead (14) transfers the energy of a defibrillator shock (15) from the implanted pulse module (10) to the surface of the heart (11)." The examiner considers this to be an energy delivery circuit that comprises a capacitor circuit; a tachyarrhythmia therapy that comprises a defibrillation therapy and a cardioversion therapy that is delivered prior to or during charging of a capacitor of the capacitor circuit.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 13-15 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill (U.S. 5,074,301). Gill discloses the claimed invention but does not disclose expressly the electrodes being intrathoracic, subcutaneous or on the housing of the implantable device. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the endocardial electrodes as taught by Gill, with the electrode arrangements as claimed, because the applicant has not disclosed the electrode arrangements provide an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the lead electrodes as taught by Gill, because they are able to effectively sense and pace the heart, as claimed. Furthermore, it is well known in the art to use intrathoracic, subcutaneous or can electrodes for the claimed purposes. Therefore, it would have been an obvious matter of design choice to modify the electrode placement to obtain the invention as specified in the claims.

7. Regarding claim 68, Gill discloses the claimed invention except for delivering pacing pulses at a rate between 5-20 pulses per minute. It would have been obvious to

one having ordinary skill in the art at the time the invention was made to deliver pacing pulses at a rate of 5-20 pulses per minute, since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

(10) Response to Argument

A. The rejection under 35 U.S.C. 102(b) of Claims 1-12 is improper because Gill fails to teach each of the claimed inventions.

1. The Appellant argues (page 8) that "the Examiner appears to take the untenable position that any pacing therapy, including Gill's bradycardia therapy, constitutes a non-physiologic, life sustaining pacing therapy." The Appellant further states that "Gill's teaching of delivering bradycardia pacing to treat asystole and restore sinus rhythm does not constitute an anticipatory teaching of a non-physiologic, life sustaining pacing therapy." To explain how Gill's device diverges from the instant application, the Appellant cites page 20 of Appellant's own Specification, and invokes the right (MPEP 2173.01) of the Appellant to be their own lexicographer by defining claimed terms in the Specification.

2. The section of the MPEP that is quoted by the Appellant reads as follows:

> A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as any special meaning assigned to a term is clearly set forth in the specification. See MPEP § 2111.01. Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the court in *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may

> not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought [emphasis added].

3. Additionally, the Examiner notes that the section of the Appellant's own Specification which is quoted states:

> Defibrillation waveforms, for example, may be monophasic, biphasic, or multiphasic (e.g., triphasic) waveforms of a known type. In an embodiment in which asystole prevention pacing is also made available, the SCDP device 502 produces pacing pulses in accordance with a non-physiologic, life sustaining pacing therapy, such as pacing therapy deliverable at a rate lower than a bradycardia pacing rate. In yet another embodiment in which anti-tachycardia pacing (ATP) is made available, the SCDP device 502 produces pacing pulses in accordance with an appropriate ATP therapy [emphasis added].

4. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). Therefore, the Examiner maintains that, although the Appellant is indeed free to define phrases and concepts used in the claims in the Specification, these definitions must make clear the metes and bounds of the claimed invention. Nowhere in the referenced paragraphs, or elsewhere in the Specification, does the Appellant specifically define what the phrase "non-physiologic, life sustaining pacing therapy" encompasses. The phrase "such as" in the cited paragraph is indefinite, and appears to present an example of one of the many possible therapies that falls under the "non-physiologic, life sustaining pacing therapy" umbrella.

5. Furthermore, the phrase "pacing therapy deliverable at a rate lower than a bradycardia pacing rate," as stated in the referenced paragraph of the Specification is also indefinite. How far below bradycardia pacing? Without defining "non-physiologic, life sustaining pacing therapy" within specific data parameters (e.g., 30-40 bpm), the exact definition within a pacing therapy regime, as defined by the Appellant, is unclear.

6. Therefore, since the Appellant has not provided a clear and precise definition of the phrase "non-physiologic, life sustaining pacing therapy," the Examiner does not consider it to be limiting; Gill's bradycardia pacing satisfies the claimed requirement.

B. The rejection under 35 U.S.C. 103(a) of Claims 13-15 and 68 is improper because Gill fails to teach or suggest each of the claimed limitations.

7. The Examiner believes that Appellants arguments regarding claims 13-15 and 68 are addressed above. With further regards to claim 68, the Appellant argues (page 12) "the non-physiologic, life sustaining pacing therapy pulses delivered at a rate between 5-20 pulses per minute is not an obvious optimization of Gill, but is instead a therapy with different goals and different parameters to effect these goals."

8. For similar reasons as listed above, the Examiner respectfully disagrees with Appellant's position that Gill's therapy has different goals from the invention as claimed. Gill's invention paces a patient's heart in order to implement a medical therapy, as does the instant application. Since, as stated above, the Examiner considers Gill's bradycardia pacing to satisfy the requirement of "non-physiologic, life sustaining pacing

therapy," the Examiner maintains that the position of obviousness of finding an optimum or workable range applies in the instant case.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Deborah L. Malamud/

Examiner, Art Unit 3766

Conferees:

/Carl H. Layno/

Supervisory Patent Examiner, Art Unit 3766

/Angela D Sykes/

Supervisory Patent Examiner, Art Unit 3762